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| APPLICATION NO. | FILING DATE | | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------|-------------|------------|----------------------|-------------------------|------------------|
| 10/775,575 | 02/09/2004 | | Rebecca Rose | 4018-1-CON-2 1469 | |
| 22442 | 7590 | 03/07/2005 | | EXAMINER | |
| SHERIDAN | | | COE, SUSAN D | | |
| 1560 BROADWAY SUITE 1200 | | | | ART UNIT | PAPER NUMBER |
| DENVER, C | O 80202 | | 1654 | | |
| | | | | DATE MAILED: 03/07/2005 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | | |
|---|--|---------------------------------|--|--|--|--|--|
| Office Action Summany | 10/775,575 · | ROSE ET AL. | | | | | |
| Office Action Summary | Examiner | Art Unit | | | | | |
| The MAN INC DATE of this communication and | Susan D. Coe | 1654 | | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sneet with the c | orrespondence address | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | |
| Status | | | | | | | |
| Responsive to communication(s) filed on <u>13 December 2004</u>. This action is FINAL. This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Disposition of Claims | | | | | | | |
| 4) Claim(s) 1-9 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-9 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | | |
| Application Papers | | | | | | | |
| 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list of | s have been received. s have been received in Applicati ity documents have been receive ı (PCT Rule 17.2(a)). | on No ed in this National Stage | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | | | | | | |

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DETAILED ACTION

1. The amendment filed December 13, 2004, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.

- 2. Claims 7-9 have been added.
- 3. Claims 1-9 are pending.

Terminal Disclaimer

4. The terminal disclaimer filed on December 13, 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent Nos. 6,709,682, 6,344,220, and 5,91,565 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claim 1 has been amended to recite limitations that are not supported by the specification as originally filed. New claims 7-9 also contain limitations that are not supported by the specification. Claims 1, 7, 8, and 9 state that the composition contains "up to 220 mg of ginger." Amounts of ginger below 50 mg are not supported by the specification because the specification only discloses using amounts between 50 and 200 mg. Claims 1, 7, and 8 state that the composition contains "up to 400 mg of turmeric." Amounts of turmeric below 50 mg are not supported by the specification because the specification only discloses using amounts between 50 and 400 mg. Claims 1, 7, 8, and 9 state that the composition contains "up to 3000 mg of yucca." Amounts of yucca below 400 mg are not supported by the specification because the specification only discloses using amounts between 400 and 3000 mg. Claim 1 states that the composition contains "up to 2000 mg of Devil's claw." Amounts of Devil's claw below 200 mg are not supported by the specification because the specification only discloses using amounts between 200 and 2000 mg.

Claim Rejections - 35 USC § 103

6. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirschhorn (*The Home Herbal Doctor* (1982), Parker Publishing Company, Inc.: New York, pp. 50-51), Hobbs (*Handbook for Herbal Healing* (January 1995), Botanica Press: California, pp. 62 and 63), Castleman (*Healing Herbs* (1991), Rodale Press: Pennsylvania, pp. 37-39, 75-78, 186-189, and 355-357), US Pat. No. 5,364,845, and US Pat. No. 3,887,703 for the reasons set forth in the previous Office action.

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All of applicant's arguments regarding this ground of rejection have been fully considered but are not deemed persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The references show that all of the claimed elements were known to be used for the same purpose; therefore, it is not considered hindsight to combine the references.

Applicant also argues that there is no motivation to arrive at the amounts for each ingredient claimed by applicant. However, the doses taught in the prior art are close in range to those claimed by applicant (see US '845, Castleman, and Hirschhorn). Therefore, since the prior art does teach using amounts that are similar to those claimed by applicant, it is not considered unreasonable that a person of ordinary skill in the art would arrive at the claimed amounts.

Applicant also argues that there is no motivation in the references themselves to combine the specific ingredients together. However, all of the claimed ingredients were known in the art at the time of the invention to have the same purpose. It has been well established that it is considered obvious to combine together one or more ingredients that are known to be useful for the same purpose. See MPEP 2144.06 which states "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order

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to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

7. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hobbs (Handbook for Herbal Healing (January 1995), Botanica Press: California, pp. 62 and 63), Castleman (Healing Herbs (1991), Rodale Press: Pennsylvania, pp. 37-39, 75-78, 186-189, and 355-357), US Pat. No. 5,364,845, and US Pat. No. 3,887,703.

Claim 7 is drawn to a composition that contains alfalfa, yucca, ginger, turmeric, black cohosh, glucosamine and mucopolysaccharides. Claim 8 is drawn to a composition that contains ginger, turmeric, yucca, alfalfa, glucosamine and mucopolysaccharides. Claim 9 is drawn to a composition that contains ginger, yucca, alfalfa, glucosamine, and mucopolysaccharides.

Hobbs teaches that yucca and turmeric have antiinflammatory activity and can be used in a preparation to treat arthritis.

Castleman teaches that alfalfa can be used to treat arthritis (see page 37). In addition, Castleman teaches that black cohosh can be used to treat arthritis (see page 77). Castleman also teaches using ginger to treat arthritis (see page 188). Furthermore, Castleman teaches that turmeric can be used to treat arthritis (see page 356).

US '845 teaches using glucosamine to treat arthritis (see claims and column 1, lines 15-23).

US '703 teaches using mucopolysaccharides to treat arthritis (see column 14, lines 8-20).

These references show that it was well known in the art at the time of the invention to use alfalfa, yucca, ginger, turmeric, black cohosh, glucosamine, and mucopolysaccharides in arthritis treating compositions. It is well known that it is prima facie obvious to combine two or more

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ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in arthritis treating compositions, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating an arthritis treating compositions. Therefore, the artisan would have been motivated to combine alfalfa, yucca, ginger, turmeric, black cohosh, glucosamine and mucopolysaccharides into a composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

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8. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.

Man D. lae 2-28-05 Susan D. Coe

Primary Examiner

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